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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------|
| 10/511,737   | 10/18/2004  | Xavier Billot        | MC059YP                         | 2557             |
| 210 7590 05/15/2007<br>MERCK AND CO., INC<br>P O BOX 2000<br>RAHWAY, NJ 07065-0907 |             |                      | EXAMINER<br>CHUNG, SUSANNAH LEE |                  |
|  |             |                      | ART UNIT                        | PAPER NUMBER     |
|  |             |                      | 1626                            |                  |
|  |             |                      | MAIL DATE                       | DELIVERY MODE    |
|  |             |                      | 05/15/2007                      | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/511,737

Applicant(s)

BILLOT ET AL.

Examiner

Susannah Chung

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1626

**DETAILED ACTION**

Claims 1-32 are currently pending in the instant application and are subject to the following new lack of unity requirement.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

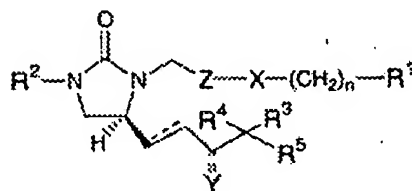
Claims 1-32 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Due to the numerous and widely divergent variables in the compound of formula (I), for example R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub>, R<sub>7</sub>, X, Y, Z, R<sub>a</sub>, R<sub>b</sub>, p, n, m, etc., a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I: Claims 1-14 and 28-29 drawn to a compound of formula (I),

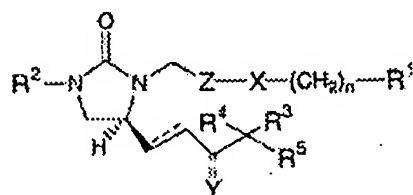


, wherein R<sub>1</sub> is tetrazole; R<sub>2</sub> is hydrogen or alkyl; R<sub>3</sub> and R<sub>4</sub>

Art Unit: 1626

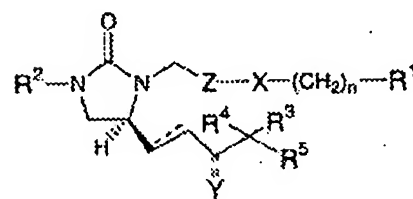
are hydrogen; R5 is phenyl; X is a bond; Y is =O or -OH; Z is (C(Rb)2)n; Rb is hydrogen, as depicted in claim 14, page 43, lines 29 and 30, (4s)-4-[(1e)-3-hydroxy-4-phenylbut-1-enyl]-1-methyl-3-[6-(1h-tetrazol-5-yl)hexyl]imidazolidin-2-one.

Group II: Claims 1-14 and 28-29 drawn to a compound of formula (I),



, wherein R1 is (CH2)pCO2R6; R6 is hydrogen or alkyl; R2 is hydrogen or alkyl; R3 and R4 are hydrogen or halogen; R5 is phenyl; X is a bond; Y is =O or -OH; Z is (C(Rb)2)n; Rb is hydrogen, as depicted in claim 14, page 46, lines 5 and 6, 7-{(5S)-5-[(1e)-4,4-difluoro-3-hydroxy-4-phenylbut-1-enyl]-2-oxoimidazolidin-1-yl}heptanoic acid.

Group III: Claims 1-14 and 28-29 drawn to a compound of formula (I),



, wherein R1 is -PO(OH)2; R2 is hydrogen or alkyl; R3 and R4 are hydrogen; R5 is phenyl; X is a bond; Y is =O or -OH; Z is (C(Rb)2)n; Rb is hydrogen, as depicted in claim 14, page 47, lines 31 and 32, 6-{(5s)-5-[(1e)-3-hydroxy-4-phenylbut-1-enyl]-2-oxoimidazolidin-1-yl}hexylphosphoric acid.

Group IV: Claims 15-27 drawn to a method of treating ocular hypertension comprising administration to a patient in need of such treatment a therapeutically effective amount of a compound of formula (I).

Group V: Claims 30-32 drawn to a use of a compound of claim 1 in the manufacture of a medicament for treating ocular hypertension.

Art Unit: 1626

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product or a method of use of said product) by identifying another specific embodiment, i.e. another value for R1, R2, R3, R4, R5, R6, R7, X, Y, Z, Ra, Rb, p, n, m, etc., not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The technical feature of the instant claim(s) is the imidazolidine ring, wherein the ring is substituted by alkyl-aryl substituents, which does not define a contribution over the prior art (as can be seen by Nefzi et al., J. Comb. Chem., 2001, 3, 68-70), which corresponds to applicants formula (I) wherein R2 is hydrogen; R1 and R5 are heteroaryl or aryl; Z is (C(Rb)<sub>2</sub>)<sub>n</sub>; and X is a bond (see Nefzi et al, page 69, scheme 1, compound 4). The variables on the imidazolidine ring vary extensively and when taken as a whole result in vastly different compounds.

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

Art Unit: 1626

A telephone call was made to Attorney Sylvia Ayler on 04/27/07 to request an oral election to the above restriction requirement, but did not result in an election being made.

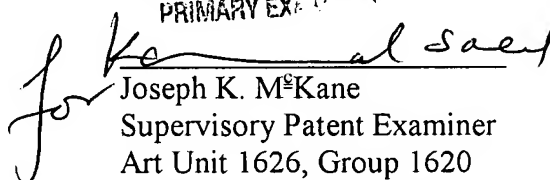
*Telephone Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Date: 3 May 2007